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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,144	02/14/2002	Doreen S. Rao	0073-077001	6889

93427 7590 05/25/2011
Brake Hughes Bellermann LLP
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402

EXAMINER

MCEVOY, THOMAS M

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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05/25/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

joe@brakehughes.com
tim@brakehughes.com
docketing@cpaglobal.com

Office Action Summary	Application No. 10/075,144	Applicant(s) RAO ET AL.	
	Examiner THOMAS MCEVOY	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,10-12,18-20 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8,9,17,22,28-31,33,34,36-39,41,42,46,48,49,51-53,60-64,66,69-76 and 85-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-12,17-20,22,23,28-31,33,34,36-39,41,42,46,48,49,51-53,60-64,66,69-76,85 and 86.

DETAILED ACTION

1. Currently claims 1, 2, 4-12, 17-20, 22, 23, 28-31, 33, 34, 36-39, 41, 42, 46, 48, 49, 51-53, 60-64, 66, 69-76, 85 and 86 are pending. Claims 4, 5, 7, 10-12, 18-20 and 23 have been withdrawn. Claims 3, 13, 16, 21, 24-27, 32, 35, 40, 43-45, 47, 54-59, 65, 67 and 68 have been cancelled. Claims 1, 2, 6, 8, 9, 17, 22, 28-31, 33, 34, 36-39, 41, 42, 46, 48, 49, 51-53, 60-64, 66, 69-76 and 85-88 are considered below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 6, 8, 9, 22, 28-31, 33, 34, 36-39, 41, 42, 46, 48, 49, 52, 53, 61-64, 69-76 and 85-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Biagi (US 6,105,392) in view of Lalieu (US 4,259,850) and Inoue (US 5,632,163).

Regarding claims 1, 2, 6, 8, 9, 22, 28, 30, 33, 34, 36, 41, 42, 46, 48, 49, 52, 53, 61-64, 69-76, and 85-88, Biagi discloses a device for treating a body canal, comprising: a device capable of medical use that includes and an elongated body portion (27 and 37) disposed between a proximal end-piece and a distal end-piece. Biagi fails to disclose interconnected loops as claimed. Biagi clearly intends any suitable ornamental earring piece to be connected to the elongated body. Lalieu discloses an ornamental piece that is well suited for connection to the Biagi elongated body. It would have been obvious to one of ordinary skill in the art to have connected the ornamental piece of Lalieu to the Biagi elongated body. It would have been obvious to one of ordinary skill in the art to have connected the ornamental piece of Lalieu to both ends of the Biagi device because the Biagi device is intended to have ornamental pieces at both ends (Figures 7 and 8, col. 7, lines 44-45) and because Lalieu suggest having the same ornamental structure on both sides of the earlobe (Figure 3). The resulting structure of this combination would comprise: a proximal end piece (28 or 40 of Lalieu) positioned at a proximal-most end of the device, the proximal end-piece defining an opening (26 of Lalieu) configured to receive at least a portion of an insertion device (20 or 22 of Lalieu); a distal end piece (spheres 28 or 40 of Lalieu) positioned at a distal-most end of the device; the end pieces having substantially the same non-looped, spherical shape; and an elongated body portion (27 or 37 of Biagi + 12 of Lalieu) disposed between the proximal end-piece and the distal end-piece; the body portion comprising a plurality of discrete, closed, circular, interconnected loops having circular cross-sections (12 of Lalieu; see Figure 2) where a proximal loop member is directly connected to the

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proximal end-piece and a distal loop member is directly connected to the distal end-piece, the end pieces configured to fit within a body canal and hold the end of the device at a specific anatomical location (since they are/would be larger than the adjacent portions of the device), each of the loops comprising a member defining at least one opening, the member of each loop passing through at least one opening of another loop to form said plurality of interconnected loops (Figure 2 and col. 3, lines 24-36 of Lalieu), and wherein the elongated body portion further comprises a substantially cylindrical non-loop segment (evident from Figures 7 and 8 of Biagi) having a distal end surface and a proximal end surface, the distal end surface being directly connected to a first loop of the interconnected loops and the proximal end surface being directly connected to a second loop of said interconnected loops, (since Applicant's loops are "directly connected" to the elongated body by a short, straight connector piece, as shown in Figures 2 and 3A, the connection of the Lalieu loops by short, straight connector 20 can be considered as a direct connection) wherein the non-loop segment is a single piece of material (evident from Figures 7 and 8 of Biagi), a diameter of at least one of the end-pieces being larger than a diameter of a remainder of the medical device (members 27 or 37 of Biagi and member 12 of Lalieu are intended to slide through a piercing while the end piece of Lalieu or Biagi is depicted as being larger than the piercing); wherein adjacent interconnected loops are moveable along each of an X, Y, and Z orthogonal axis relative to each other at least during deployment of the medical device in the body canal (Figure 2 and col. 3, lines 24-36 of Lalieu), the substantially cylindrical non-loop segment defines a longitudinal axis, a radial center of the

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substantially cylindrical non-loop segment extends along the longitudinal axis, the first loop of the interconnected loops and the second loop of the interconnected loops extend along the longitudinal axis (the chain and end pieces of Lalieu could be aligned with the elongated body of Biagi as claimed), wherein it would have been obvious to one of ordinary skill in the art to have made the elongated body of plastic (a compressible material) since Biagi effectively discloses that parts which contact the piercing interior could be made of a hypoallergenic plastic (col. 4, lines 39-41 and elsewhere). Biagi in view of Lalieu fail to disclose an undulating surface on the non-loop segment as claimed. Inoue discloses a non-loop segment having an undulating surface (Figure 6) in order to retain liquid for treating an infected earlobe or for removing fluids from an infected earlobe (col. 5, lines 1-12). Inoue discloses that the non-loop segment can be worn as a permanent earring (col. 3, lines 56-57; col. 4, lines 32-34) and can contain ornamental decorations (e.g. member 44). Inoue discloses that the non-loop segment does not require a backing member (col. 4, lines 28-31). Therefore, it would have been obvious to one of ordinary skill in the art in view of Inoue to have provided an undulating surface to the non-loop segment of Biagi in order to treat an infected earlobe. Since Inoue discloses that the non-loop segment should be sized to match the width of the earlobe (col. 4, line 29), the undulating surface should extend completely across the earlobe (Figure 9) and Lalieu discloses that the interconnected loops should extend all the way to the earlobe (Figure 3), it would have been obvious to one of ordinary skill in the art to have sized the non-loop segment to match the width of the earlobe and to have provided the undulations along the entire length of the non-loop segment.

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Regarding claims 17, 60 and 66, Biagi in view of Lalieu fail to disclose that the loops are biodegradable. Both Biagi and Lalieu suggest making the device from hypoallergenic materials (see col. 2, line 61 of Lalieu for example). Inoue teaches that an earring can be coated with certain materials which are biodegradable in order to prevent an allergic reaction (col. 3, lines 35-39; col. 4, lines 38-44). Therefore, it would have been obvious to one of ordinary skill in the art to have coated the above device with the hypoallergenic materials of Inoue in order to prevent allergic reactions. Regarding claim 29, the end-pieces are capable of holding the respective end of the device at the claimed locations. Regarding claim 31, it would have been obvious to one of ordinary skill in the art to have soldered member 40 to the proximal and distal loop member because Lalieu discloses that sphere 18 is soldered (col. 2, lines 65-66) to an end loop and the Figure 6 embodiment does not use an end member 18 to secure the ornament. Regarding claims 37 and 38, each of the plurality of interconnected loops is configured to move within the confines of the opening of an adjacent loop and to permit fluid to pass through the opening (evident from Figure 2 of Lalieu). Regarding claim 39, the axial length of the body would be adjustable because the chain of Lalieu is axially adjustable. Regarding claim 51, the segment is substantially tubular inasmuch as Applicant's elongate body of the elected embodiment is tubular. Furthermore, see col. 7, lines 49-50 of Biagi.

Response to Arguments

5. Applicant's arguments filed March 7th 2011 have been considered but are not persuasive. Applicant has argued that neither Biagi nor Lalieu discloses the opening as recited in the newly added limitations. Examiner respectfully disagrees and has explained above how these limitations are met. The claimed opening must be differentiated from the opening disclosed by Lalieu.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS MCEVOY whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
5/22/11